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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/544,004

Filing Date: May 08, 2000

Appellant(s): DURAISWAMI ET AL.

J. Mitchell Jones
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed April 17, 2006 appealing from the Office action mailed June 29, 2005.

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(1) (1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The following are the related appeals, interferences, and judicial proceedings known to the examiner which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal:

U.S. Patent Application Serial NO. 09/271,024;

U.S. Patent Application Serial NO. 09/132,593.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

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The copy of the appealed claims contained in the Appendix to the brief is correct.

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(8) Evidence Relied Upon

The following is a listing of the evidence (e.g., patents, publications, Official Notice, and admitted prior art) relied upon in the rejection of claims under appeal.

US Patent 5,760,082	Cook et al.	June 2, 1998
US Patent 6,159,525	Lievense et al.	December 12, 2000
US Patent 6,034,132	Remmereit	March 7, 2000
US Patent 6,524,527	Fimreite et al.	February 25, 2003
WO 97/18320	Cain et al.	May 22, 1997

(9) Grounds of Rejection

Initially, it is noted that elected species of metal chelators for examining purpose is ascorbic acid (vitamin C) (response filed July 12, 2001).

Double Patenting Rejections

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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2. Claims 10-19, 24-34 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2, 3 and 8-22 of U.S. Patent No. 6,524,527. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims herein are generic to the claims in '527. Particularly, claims 2, 3 and 8-22 read on stable CLA composition (with limited amount of VOC) comprising vitamins, i.e., mixture of vitamins, the mixture of vitamins is construed as comprising vitamin C (metal chelator), vitamins A and E (antioxidants). See, example 21 at column 34.

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Claim Rejections 35 U.S.C. §103

- 1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 2. Claims 1-5, 10-19, 24-30 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over both Cook et al. (U.S. Patent 5,760,082, IDS) and Lievense et al. (U.S. patent 6,159,525) in view of Cain et al. (WO 97/18320, IDS), Remmereit (6,034,132), and in further view of applicants' admission.
- 3. Cook teaches a food product containing conjugated linoleic acids, their esters, salts or mixtures. The linoleic acid compounds may be from corn oil, safflower etc. the food products may further containing vitamins. See, particularly, the abstract, column 1, lines 10-13, lines 49-60. Column 2, lines 51-67, Examples 3 and 5. Cook further teaches that conjugated linoleic acid

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may be incorporated into various food products. See column 5, lines 6-14. Lievense et al teaches a food products comprising CLA compounds which has sensoric properties as good as corresponding food product without CLA.

4. The primary references do not teach expressly the employment of a combination of antioxidant and metal (oxidant) chelator, such ascorbic acid and lecithin, or the use of a commercial antioxidant product, Controx, or particularly point out the amount of VOC.

However, Cain teaches that CLA is known to be sensitive to oxygen and addition of antioxidant to a composition comprising CLA is recommended. The antioxidants are selected from the groups consisting of tocopherols, TBHQ, BHT, BHA, free radical scavengers, propylgallate, ascorbylesters of fatty acids. See, page 6, lines 29-36 and claims 10 and 13-15. Remmereit also teaches that CLA is susceptible to oxidation and it is desirable to add suitable antioxidants to CLA composition for human use. Among the recommended antioxidants are tocopherol, lecithin, ascorbate etc (col.5, lines 10-13). Further, applicants admitted that some commercial antioxidant comprising both tocopherol and lecithin. See page 23 herein.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to employ vitamin C, lecithin, and tocopherol, such as those commercial antioxidant composition, in the CLA composition, or food products in Cook or Lievense.

A person of ordinary skill in the art would have been motivated to employ vitamin C in the composition, or food products in Cook or Lievense because vitamins are known to be useful with CLA in food products, and tocopherol, lecithin, and vitamin C are those of well-known antioxidants which are known to be useful in CLA composition for stabilizing CLA compounds.

As to the employ of two of the known antioxidants, note, it is prima facie obvious to combine two compositions each of which is taught in the prior art to be useful for same purpose in order to form third composition that is to be used for very the same purpose; idea of combining them flows logically from their having been individually taught in prior art; thus, the claimed invention which is a combination of two known antioxidants sets forth prima facie obvious subject matter. See In re Kerkhoven, 205 USPQ 1069. Regarding to the limitation about the amount of VOC, since the prior art teach that the food products containing CLA do not have any sensoric property caused by VOC, the amount of VOC is reasonably believed to be very low. The amount of VOC claimed herein is either within the scope of the prior art, or an obvious variation of the prior art, lacking the criticality to the final products. Regarding the particular function of vitamin C claimed herein, i.e., metal chelator, note the intended function of a component in a composition would not render any patentable weight to the composition.

(10) Response to Argument

A prima facie case of obviousness has been established.

Appellants contend that

"It is well-established case law that a prima facie case of obviousness requires a reference or combination of references *teach or suggest* all of the elements of the claimed invention. See, e.g., *Northern Telecom Inc. v. Datapoint Corp.*, 15 USPQ2d 1321, 1323 (Fed. Cir. 199%. Here, the Examiner admits that the Cook, Lievense, Cain and Remmereit references fail to teach compositions, food products, or food supplements comprising an isomerized conjugated linoleic acid moiety, at least one free radical scavenger, and at least one metal chelator: "The primary references do not teach expressly the employment of a combination of antioxidant and metal (oxidant) chelator, such as ascorbic acid and lecithin, or the use of a commercial antioxidant product, Controx, or particularly point out the amount of VOC." Office Action dated June 29,

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2005, page 3 (Paper No. 26). As such, the cited references do not teach all of the elements of Claims 1-5, 10-19, 24-30 and 39." (Emphasis added)

Apparently, appellants misread "teach or suggest" as "teach" only, which is not a proper standard of establishing a prima facie case of obviousness. Further, as it is well-settled that question under 35 U.S.C. 103 is not merely what reference expressly teach, but what they would have suggested to one of ordinary skill in the art at the time the invention was made; all disclosures of prior art, including unpreferred embodiments, must considered. In re Lamberti and Konort (CCPA), 192 USPQ 278. As discussed in the rejections the employment of two well-known antioxidants in CLA composition would have been obvious to one of ordinary skill in the art.

In response to appellant's argument that one of the antioxidant is used as metal chelator, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

The references herein relied upon establish a strong <u>prima facie</u> case of obviousness as to applicants' invention. The claimed subject matter is of such a nature that the differences between said subject matter, and the teachings of the prior art of record, would have rendered applicants' subject matter, as a whole, obvious to those skilled in the art at the time of applicants' invention. The references clearly establish that the claim designated components were old, of known character and that one skilled in the art would have been motivated to employ said components in the manner herein claimed to obtain the claimed, expected results. The claims are therefore

properly rejected under 35 USC 103. Appellants' arguments fail to reach the instant rejections core issue; that concomitantly employing compounds, old and well known for the same use is obvious to the skilled artisan. To overcome this rejection Applicants must illustrate the presence of unexpected benefits in the resulting mixture. Any combination not shown to possesses such unexpected benefits must remain properly rejected as obvious. In illustrating unexpected therapeutic benefits the Applicant must test all active components individually to ensure a greater than additive therapeutic benefit.

Appellants fail to provide convincing evidence to rebut the obvious rejections

As discussed above, a prima facie case of obviousness has been established, the only way to overcome the rejections is to present secondary evidence.

Appellants assert that the claimed invention lies in the discovery of the source of a problem unrecognized in the prior art, however, fail to provide convincing evidence to substantiate the assertion.

Appellants contend that:

"The Saebo Declaration is not solely directed to evidence of unexpected results. Instead, the Saebo Declaration provides evidence supporting the facts that a) prior art methods of stabilization with just one compound such as ascorbic acid are insufficient (i.e., there is a problem); b) that applicant's solved the problem; and c) that the prior art compositions necessarily contained high levels of VOCs because the problem had not been solved."

Appellants' arguments are not persuasive. Particularly, a) no references in the art teach that the antioxidants employed in CLA composition has to be single compound not a mixture. In fact Remercit fairly suggest that a mixture of antioxidants may be used. Particularly, Remercit states "CLA is also susceptible to oxidation. Therefore, it is desirable to package CLA for human use

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with suitable *antioxidants* such as lecithin, tocopherol, ascorbate, ascorbyl palmitate or spiece extracts such as rosemary extract." (Col. 5, lines 10-13, emphasis added); b) Appellants have not established a prima facie case that they actually have identified the source of problems unresolved in the prior art. Only data provided in the 132 declaration is that mixture of citric acid and an antioxidant provides better antioxidant efficacy. It is not clear if the improvement is from an additive effect or a synergistic effect. Based on this single-point data, one of skilled artisan can not extrapolate to the scope as herein claimed, i.e. any combination of two compounds, wherein at least one may function as metal chelator and one as antioxidant. The data does not commensurate in scope with claimed invention. Further, the data can not explain why use ascorbic acid alone would not effective, considering that ascorbic acid may function both as metal chelator and antioxidant. C) appellants have not shown that prior art CLA composition as suggested by the cited references would necessarily contained high levels of VOC.

In response to appellant's argument that vitamin C and lecithin function as metal chelator, which has not been recognized before the claimed invention, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). The cited references particularly suggest the employment of lecithin, tocopherols, ascorbate, such as rosemary extract, for stabilizing CLA composition (see, e.g., col. 5, lines 10-13 in Remmereit). One of ordinary skill in the art would have been motivated to use combination of them or any well known composition that comprising those ingredients for stabilizing CLA containing composition. The instant claims are directed to effecting a biochemical pathway with an old and well known

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compounds. The argument that such claims are not directed to the old and well known ultimate

utility (stabilizing CLA) for the compounds, e.g., lecithin or vitamin C, are not probative. It is

well settled patent law that mode of action elucidation does not impart patentable moment to

otherwise old and obvious subject matter. Applicant's attention is directed to In re Swinehart,

(169 USPQ 226 at 229) where the Court of Customs and Patent Appeals stated "is elementary

that the mere recitation of a newly discovered function or property, inherently possessed by thing

in the prior art, does not cause a claim drawn to those things to distinguish over the prior art."

The ultimate utility for the claimed compounds is old and well known rendering the claimed

subject matter obvious to the skilled artisan. It would follow therefore that the instant claims are

properly rejected under 35 USC 103.

(11) Related Proceeding(s) Appendix

Copies of the court or Board decision(s) identified in the Related Appeals and

Interferences section of this examiner's answer are provided by appellants.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Shengjun Wang

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